Amendments to the Claims

+3032680065

1.-31. (cancelled)

- (new) A condensation aerosol for delivery of a drug selected from the group 32. consisting of bumetanide, ethacrynic acid, furosemide, muzolimine, spironolactone, torsemide, triamterene, tripamide, BG 9928 and BG 9719, wherein the condensation aerosol is formed by heating a thin film containing the drug, on a solid support, to produce a vapor of the drug, and condensing the vapor to form a condensation aerosol characterized by less than 10% drug degradation products by weight, and an MMAD of less than 5 microns.
- (new) The condensation aerosol of Claim 1, wherein the condensation aerosol is 33. formed at a rate greater than 10⁹ particles per second.
- (new) The condensation aerosol of Claim 2, wherein the condensation aerosol is 34. formed at a rate greater than 10¹⁰ particles per second.
- 35. (new) The condensation aerosol of Claim 1, wherein the condensation aerosol is characterized by an MMAD of less than 3 microns.
- (new) The condensation aerosol of Claim 1, wherein the condensation aerosol is 36. characterized by an MMAD of 1 to 3.5 microns.
- (new) The condensation aerosol of Claim 1, wherein the condensation aerosol is 37. characterized by less than 5% drug degradation products by weight.
- (new) The condensation aerosol of Claim 37, wherein the condensation aerosol is 38. characterized by less than 2.5% drug degradation products by weight.
- **39**. (new) The condensation aerosol of Claim 37, wherein the condensation aerosol is characterized by an MMAD of 1 to 3.5 microns and wherein the drug is burnetanide.

Serial No. 10/712,365 8 Attorney Docket No. 00065.01R

40. (new) The condensation aerosol of Claim 1, wherein the solid support is a metal foil.

+3032680065

- 41. (new) The condensation aerosol of Claim 1, wherein the drug is bumetanide.
- 42. (new) The condensation aerosol of Claim 1, wherein the drug is ethacrynic acid.
- (new) The condensation aerosol of Claim 1, wherein the drug is furosemide. 43.
- 44. (new) The condensation aerosol of Claim 1, wherein the drug is muzolimine.
- 45. (new) The condensation aerosol of Claim 1, wherein the drug is spironolactone.
- 46. (new) The condensation aerosol of Claim 1, wherein the drug is torsemide.
- (new) The condensation aerosol of Claim 1, wherein the drug is triamterene. 47.
- (new) The condensation aerosol of Claim 1, wherein the drug is tripamide. 48.
- 49. (new) The condensation aerosol of Claim 1, wherein the drug is BG 9928.
- 50. (new) The condensation aerosol of Claim 1, wherein the drug is BG 9719.
- 51. (new) A method of producing a drug selected from the group consisting of bumetanide, ethacrynic acid, furosemide, muzolimine, spironolactone, torsemide, triamterene, tripamide, BG 9928 and BG 9719, in an aerosol form comprising:
- a. heating a thin film containing the drug, on a solid support, to produce a vapor of the drug, and

FROM-Swanson & Bratschun LLC

- providing an air flow through the vapor to form a condensation aerosol characterized by less than 10% drug degradation products by weight, and an MMAD of less than 5 microns.
- 52. (new) The method of Claim 51, wherein the condensation aerosol is formed at a rate greater than 10⁹ particles per second.
- 53. (new) The method of Claim 52, wherein the condensation aerosol is formed at a rate greater than 10¹⁰ particles per second.
- (new) The method of Claim 51, wherein the condensation aerosol is characterized 54. by an MMAD of less than 3 microns.
- 55. (new) The method of Claim 51, wherein the condensation aerosol is characterized by an MMAD of 1 to 3.5 microns.
- 56. (new) The method of Claim 51, wherein the condensation aerosol is characterized by less than 5% drug degradation products by weight.
- 57. (new) The method of Claim 56, wherein the condensation aerosol is characterized by less than 2.5% drug degradation products by weight.
- 58. (new) The method of Claim 56, wherein the condensation aerosol is characterized by an MMAD of 1 to 3.5 microns and wherein the drug is bumetanide.
 - 58. (new) The method of Claim 51, wherein the solid support is a metal foil.
 - 60. (new) The method of Claim 51, wherein the drug is bumetanide.
 - 61. (new) The method of Claim 51, wherein the drug is ethacrynic acid.

Serial No. 10/712,365 10 Attorney Docket No. 00065.01R

F-538

15:45

+3032680065

- 62. (new) The method of Claim 51, wherein the drug is furosemide.
- 63. (new) The method of Claim 51, wherein the drug is muzolimine.
- 64. (new) The method of Claim 51, wherein the drug is spironolactone.
- 65. (new) The method of Claim 51, wherein the drug is torsemide.
- 66. (new) The method of Claim 51, wherein the drug is triamterene.
- 67. (new) The method of Claim 51, wherein the drug is tripamide.
- 68. (new) The method of Claim 51, wherein the drug is BG 9928.
- 69. (new) The method of Claim 51, wherein the drug is BG 9719.
- 70. (new) A method of treating edema in a patient comprising administering a therapeutic amount of a drug condensation aerosol to the patient by inhalation,

wherein the drug is selected from the group consisting of bumetanide, ethacrynic acid, furosemide, muzolimine, spironolactone, torsemide, triamterene, tripamide, BG 9928 and BG 9719, and

wherein the condensation aerosol is formed by heating a thin film containing the drug, on a solid support, to produce a vapor of the drug, and condensing the vapor to form a condensation aerosol characterized by less than 10% drug degradation products by weight, and an MMAD of less than 5 microns.

- 71. (new) The method of Claim 70, wherein the condensation aerosol is characterized by an MMAD of less than 3 microns.
- 72. (new) The method of Claim 70, wherein the condensation aerosol is characterized by an MMAD of 1 to 3.5 microns.

Serial No. 10/712,365 11 Attorney Docket No. 00065.01R 05-17-06

(new) The method of Claim 70, wherein the condensation aerosol is characterized 73.

+3032680065

74. (new) The method of Claim 70, wherein peak plasma drug concentration is reached in less than 0.1 hours.

by less than 5% drug degradation products be weight and wherein the drug is bumetanide.

- 75. (new) The method of Claim 70, wherein the condensation aerosol is formed at a rate greater than 0.5 mg/second.
- (new) The method of Claim 70, wherein at least 50% by weight of the 76. condensation aerosol is amorphous in form.
- 77. (new) The method of Claim 70, wherein the therapeutic amount of a drug condensation aerosol comprises between 0.1 mg and 10 mg of bumetanide delivered in a single inspiration.
- 78. (new) The method of Claim 70, wherein the therapeutic amount of a drug condensation aerosol comprises between 10 mg and 100 mg of ethacrynic acid delivered in a single inspiration.
- 79. (new) The method of Claim 70, wherein the therapeutic amount of a drug condensation aerosol comprises between 10 mg and 200 mg of muzolimine delivered in a single inspiration.
- 80. (new) The method of Claim 70, wherein the therapeutic amount of a drug condensation aerosol comprises between 1 mg and 150 mg of torsemide delivered in a single inspiration.

81. (new) The method of Claim 70, wherein the therapeutic amount of a drug condensation aerosol comprises between 1 mg and 25 mg of tripamide delivered in a single inspiration.

+3032680065

- 82. (new) The method of Claim 70, wherein the therapeutic amount of a drug condensation aerosol comprises between 1 mg and 25 mg of delivered in a single inspiration.
- 83. (new) A method of treating congestive heart failure in a patient comprising administering a therapeutic amount of a drug condensation aerosol to the patient by inhalation,

wherein the drug is selected from the group consisting of bumetanide, ethacrynic acid, furosemide and torsemide, and

wherein the condensation aerosol is formed by heating a thin film containing the drug, on a solid support, to produce a vapor of the drug, and condensing the vapor to form a condensation aerosol characterized by less than 10% drug degradation products by weight, and an MMAD of less than 5 microns.

- 84. (new) The method of Claim 83, wherein the condensation aerosol is characterized by an MMAD of less than 3 microns.
- 85. (new) The method of Claim 83, wherein the condensation aerosol is characterized by an MMAD of 1 to 3.5 microns.
- 86. (new) The method of Claim 85, wherein the condensation aerosol is characterized by less than 5% drug degradation products be weight and wherein the drug is burnetanide.
- 87. (new) The method of Claim 83, wherein peak plasma drug concentration is reached in less than 0.1 hours.
- 88. (new) The method of Claim 83, wherein the condensation aerosol is formed at a rate greater than 0.5 mg/second.

Serial No. 10/712,365 13 Attorney Docket No. 00065.01R 89. (new) The method of Claim 83, wherein at least 50% by weight of the condensation aerosol is amorphous in form.

FROM-Swanson & Bratschun LLC

- 90. (new) The method of Claim 83, wherein the therapeutic amount of a drug condensation aerosol comprises between 0.1 mg and 10 mg of bumetanide delivered in a single inspiration.
- 91. (new) The method of Claim 83, wherein the therapeutic amount of a drug condensation aerosol comprises between 10 mg and 100 mg of ethacrynic acid delivered in a single inspiration.
- 92. (new) The method of Claim 83, wherein the therapeutic amount of a drug condensation aerosol comprises between 10 mg and 200 mg of muzolimine delivered in a single inspiration.
- 93. (new) The method of Claim 83, wherein the therapeutic amount of a drug condensation aerosol comprises between 1 mg and 150 mg of torsemide delivered in a single inspiration.
- 94. (new) The method of Claim 83, wherein the therapeutic amount of a drug condensation aerosol comprises between 1 mg and 25 mg of triamterene delivered in a single inspiration.
- 95. (new) A method of administering a drug condensation aerosol to a patient by inhalation,

wherein the drug is selected from the group consisting of bumetanide, ethacrynic acid, furosemide, muzolimine, spironolactone, torsemide, triamterene, tripamide, BG 9928 and BG 9719, and

wherein the drug condensation aerosol is formed by heating a thin film containing the drug, on a solid support, to produce a vapor of the drug, and condensing the vapor to form a

96. (new) The method of Claim 95, wherein the drug is bumetanide.

FROM-Swanson & Bratschun LLC

- 97. (new) The method of Claim 95, wherein the drug is ethacrynic acid.
- 98. (new) The method of Claim 95, wherein the drug is furosemide.
- 99. (new) The method of Claim 95, wherein the drug is muzolimine.
- 100. (new) The method of Claim 95, wherein the drug is spironolactone.
- 101. (new) The method of Claim 95, wherein the drug is torsemide.
- 102. (new) The method of Claim 95, wherein the drug is triamterene.
- 103. (new) The method of Claim 95, wherein the drug is tripamide.
- 104. (new) The method of Claim 95, wherein the drug is BG 9928.
- 105. (new) The method of Claim 95, wherein the drug is BG 9719.
- 106. (new) A kit for delivering a drug condensation aerosol comprising:
- a thin film containing the drug, on a solid support, wherein the drug is selected from the group consisting of bumetanide, ethacrynic acid, furosemide, muzolimine, spironolactone, torsemide, triamterene, tripamide, BG 9928 and BG 9719, and
- b. a device for providing the condensation aerosol, wherein the condensation aerosol is formed by heating the thin film to produce a vapor of the drug, and condensing the vapor to form a condensation aerosol characterized by less than 10% drug degradation products by weight, and an MMAD of less than 5 microns.

Serial No. 10/712,365 15 Attorney Docket No. 00065.01R

- 107. (new) The kit of Claim 106, wherein the device comprises:
- a flow through enclosure containing the solid support, a.
- . b. a power source that can be activated to heat the solid support, and
- at least one portal through which air can be drawn by inhalation. c.

wherein activation of the power source is effective to produce a vapor of the drug, and drawing air through the enclosure is effective to condense the vapor to form the condensation aerosol.

+3032680065

- 108. (new) The kit of Claim 107, wherein the heat for heating the solid support is generated by an exothermic chemical reaction.
- 109. (new) The kit of Claim 108, wherein the exothermic chemical reaction is oxidation of combustible materials.
- 110. (new) The kit of Claim 107, wherein the heat for heating the solid support is generated by passage of current through an electrical resistance element.
- 111. (new) The kit of Claim 107, wherein the solid support has a surface area dimensioned to accommodate a therapeutic dose of the drug.
- (new) The kit of Claim 106, wherein peak plasma drug concentration is reached in 112. less than 0.1 hours.
 - 113. (new) The kit of Claim 106, further including instructions for use.
- (new) The kit of Claim 106, wherein the condensation aerosol is characterized by an MMAD of less than 3 microns.
- (new) The kit of Claim 106, wherein the condensation aerosol is characterized by an MMAD of 1 to 3.5 microns.

Serial No. 10/712,365 16 Attorney Docket No. 00065.01R

05-17-06

15:47

- 116. (new) The condensation aerosol of Claim 115, wherein the condensation aerosol is characterized by less than 5% drug degradation products be weight and wherein the drug is burnetanide.
 - 117. (new) The kit of Claim 106, wherein the drug is bumetanide.
 - 118. (new) The kit of Claim 106, wherein the drug is ethacrynic acid.
 - 119. (new) The kit of Claim 106, wherein the drug is furosemide.
 - 120. (new) The kit of Claim 106, wherein the drug is muzolimine.
 - 121. (new) The kit of Claim 106, wherein the drug is spironolactone.
 - 122. (new) The kit of Claim 106, wherein the drug is torsemide.
 - 123. (new) The kit of Claim 106, wherein the drug is triamterene.
 - 124. (new) The kit of Claim 106, wherein the drug is tripamide.
 - 125. (new) The kit of Claim 106, wherein the drug is BG 9928.
 - 126. (new) The kit of Claim 106, wherein the drug is BG 9719.
- 127. (new) The kit of Claim 106, wherein the solid support has a surface to mass ratio of greater than 1 cm² per gram.
- 128. (new) The kit of Claim 106, wherein the solid support has a surface to volume ratio of greater than 100 per meter.

05-17-06

T-266 P.019

- 129. (new) The kit of Claim 106, wherein the solid support is a metal foil.
- (new) The kit of Claim 129, wherein the metal foil has a thickness of less than 130. 0.25 mm.